

REMARKS

In the Office Action, claim 9 is objected to; claims 1, 3-9, 11-13, 16-19, 21, 23, and 25-28 are rejected under 35 U.S.C. §103; and claims 20, 22 and 24 have been further objected. Claims 9, 20, 22, and 24 has been canceled without prejudice or disclaimer; and claims 29-31 have been newly added. Applicants believe that the rejections and objections should be withdrawn based on at least the reasons set forth below.

At the outset, claims 20, 22 and 24 have been objected but would be allowable if rewritten in independent form. See, Office Action, page 3. In response, Applicants have added new claims 29-31. Claims 29-31 represent claims 20, 22 and 24 in independent form. Claims 20, 22 and 24 have been canceled without prejudice or disclaimer as previously discussed. Therefore, claims 29-31 should be allowed.

Further, claim 9 has been objected as of being of improper dependent form. See, Office Action, page 2. As previously discussed, claim 9 has been canceled without prejudice or disclaimer. Thus, this objection should be withdrawn.

In the Office Action, claims 1, 3-9, 11-13, 16-19, 21, 23, and 25-28 are rejected under 35 U.S.C. §103 in view of Patent Publication No. 673,063 (Medical Research) and further in view of PCT Patent Publication No. WO 93/08830 (Barani) and Publication No. XP-000914255 (Kaishi). The Patent Office primarily relies on Medical Research and thus further relies on Barani and Kaishi allegedly to remedy the deficiencies of same.

Applicants respectfully submit that this rejection is not proper. At the outset, claim 9 has been cancelled without prejudice or disclaimer as previously discussed. Thus, the rejection has been rendered moot and should be withdrawn with respect to same. Of the remaining pending claims at issue, claims 1, 8, 13, 19, 21, 23 and 25 are the sole independent claims. Claim 1 recites an iron-protein hydrolysate complex. The complex includes ferrous ions chelated to partially hydrolyzed egg white protein that has a molecular weight in the range of about 2,000 to about 6,000. Claim 8 recites an iron-protein hydrolysate complex. The complex includes ferrous ions chelated to partially hydrolyzed egg white protein which is a microbial protease hydrolyzate wherein the microbial protease contains both endo-peptidase and exo-peptidase, and wherein the partially hydrolyzed egg white protein has a molecular weight in the range of about 2,000 to about 6,000.

Claim 13 recites an iron-protein hydrolysate complex. The complex includes ferrous ions chelated to partially hydrolyzed egg white protein wherein the complex contains about 1% to about 10% by dried weight of ferrous ions, and wherein the partially hydrolyzed egg white protein has a molecular weight in the range of about 2,000 to about 6,000. Claim 19 recites a sterilized liquid beverage which contains lipid and a stable iron fortification system. The iron fortification system includes an iron-protein hydrolysate complex of ferrous ions chelated to partially hydrolyzed egg white protein, wherein the partially hydrolyzed egg white protein has a molecular weight in the range of about 2,000 to about 6,000. Claim 21 recites a sterilized liquid beverage which contains polyphenols and a stable iron fortification system. The iron fortification system includes an iron-protein hydrolysate complex of ferrous ions chelated to partially hydrolyzed egg white protein, wherein the partially hydrolyzed egg white protein has a molecular weight in the range of about 2,000 to about 6,000.

Claim 23 recites a beverage powder which contains lipid and a stable iron fortification system. The iron fortification system includes an iron protein hydrolysate complex of ferrous ions chelated to partially hydrolyzed egg white protein. Claim 25 recites a process for preparing an iron fortification system. The process includes enzymatically hydrolyzing an egg white protein using a microbial protease to provide a partially hydrolyzed egg white protein; adding a ferrous source to the partially hydrolyzed egg white protein under acidic conditions; and raising the pH to 6.5 to 7.5 for forming a ferrous-hydrolyzed egg white protein complex as the iron fortification system, wherein the partially hydrolyzed egg white protein has a molecular weight in the range of about 2,000 to about 6,000.

The present invention is based on the discovery that partially hydrolyzed egg white protein is able to strongly complex with ferrous ions and yet provide the iron in a bioavailable form. Iron complexes that are prepared from partially hydrolyzed egg white with a molecular weight that ranges from about 2,000 to about 6,000 are very stable. The resulting iron complexes have a reduced ability to cause deleterious effects, such as lipid oxidation, color degradation, and vitamin C degradation. This makes the iron complexes an ideal vehicle for fortifying foods and beverages, particularly foods and beverages that can improve nutritional status. See, specification, page 5, line 22 to page 6, line 6.

In contrast, Applicants believe that the cited art even if combinable is distinguishable from the claimed invention. At the outset, Applicants believe that the primary Medical Research reference is deficient with respect to an iron-protein hydrolysate complex that includes ferrous ions chelated to partially hydrolyzed egg white protein that has a molecular weight in the range of about 2,000 to about 6,000 as claimed. For example, the emphasis of this reference relates to the preparation of an admixture of free amino acids that can then be reacted with an iron compound. See, Medical Research, page 1, lines 54-80; page 2, lines 23-25; and page 2, lines 29-30. Clearly, this suggests that Medical Research favors the complete hydrolysis of protein in contrast to the partially hydrolyzed egg white protein at the specific molecular weight range as claimed. Indeed, Applicants have found that iron complexes which are prepared from intact egg white protein or extensively hydrolyzed egg white protein are not sufficiently strong. See, specification, page 6, lines 3-5.

Further, the Medical Research reference provides that any protein substance may be employed as a starting material and also includes a laundry list of examples thereof. See, Medical Research, page 1, lines 81-85. Moreover, this reference merely provides gelatine as the starting material as disclosed in the sole example. See, Medical Research, page 2, lines 57-62. Again, Applicants have discovered that partially hydrolyzed egg white protein at a specific molecular weight as claimed can strongly complex with ferrous ions and further provide the iron in a bioavailable form as previously discussed. Therefore, the Medical Research reference on its own is clearly distinguishable from the claimed invention.

With respect to the remaining cited references, Applicants do not believe that Barani and Kaishi can be relied on solely to remedy the deficiencies of the Medical Research reference. Indeed, the Patent Office has merely relied on these references allegedly to show the limitations of the dependent claims. See, Office Action, page 2.

Further, Applicants do not believe that one skilled in the art would be inclined to modify the Medical Research reference in view of the teachings of Barani and Kaishi. With respect to Barani, this reference provides that the process step of acylation is an essential feature where hydrolysis is merely an optional feature. See, Barani, p. 4, lines 25 to p. 5, line 3. Indeed, Applicants have surprisingly found that by partial hydrolysis of egg white protein to a specific molecular weight range of 2,000 to 6,000, this results in a highly complex capacity of iron which does not require the isolation procedure and the subsequent acylation step as disclosed in Barani.

Therefore, Applicants believe that the present invention provides surprising and unexpected results over Barani.

With respect to Kaishi, the primary emphasis of this reference relates to the antioxidant activity of hydrolysates of four different proteins that use eight different proteases. In Kaishi, egg white albumin that was hydrolyzed according to Amano S displayed the highest antioxidant activity. From this hydrolysate, three specific peptides were isolated and their antioxidant effects were compared. Indeed, iron was merely used as a tool to obtain a measure of antioxidant activity where Kaishi further fails to mention the preparation of a stable complex to fortify foodstuffs, let alone one that includes iron. See, Kaishi, Abstract and figures. Clearly, this suggest that Kaishi fails to recognize the problem of providing iron protein complexes for providing iron as a trace element in human and animal nutrition in contrast as Applicants' claimed invention has addressed.

Further, Applicants believe that the most active peptide (P1) disclosed in Kaishi includes three amino acids with a molecular weight that is well below the lower limit molecular weight of about 2000 as claimed. Indeed, the P1 peptide was twice as active as both another peptide of a similar size (P2) and a much larger peptide (P3). See, Kaishi, Abstract and figures. Clearly, Kaishi is distinguishable from the claimed invention to the extent that it teaches away from same for at least these reasons.

What the Patent Office has done is to rely on hindsight reasoning in support of the obviousness rejection. Again, the Medical Research reference is deficient, at a minimum, with respect to a partially hydrolyzed egg white protein at a molecular weight as claimed. Again, the focus of this reference relates to an admixture of free amino acids, and thus the complete hydrolysis of protein. Further, the emphasis of Barani relates to the isolation and acylation of a specific type of egg protein where hydrolysis is merely regarded as an optional process feature. Moreover, the Kaishi reference suggests that a low molecular weight peptide displays better antioxidant activity and further even fails to mention the preparation of a stable complex thereof, let alone a stable iron complex thereof, thus effectively teaching away from the claimed invention as previously discussed. Therefore, Applicants do not believe that one skilled in the art would be motivated to combine and/or modify the cited art to arrive at the claimed invention.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art even if combinable fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of the present application in view of same.

Respectfully submitted,

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